REMARKS

The present communication responds to the Office Action dated April 17, 2006. With that action, the Examiner vacated the Office Action dated December 30, 2005.

The applicant concurs with the Examiner's summary of the telephone interview of January 23, 2006. During that interview, the applicant's representative, Alicia Griffin Mills, and the Examiner discussed the Office Action of December 30, 2005, in which not all of the pending claims were addressed. The Examiner indicated he would issue a new Office Action, thus vacating the December 30, 2005 Office Action. The new Office Action, dated April 17, 2006, is responded to herewith.

In the April 17, 2006 Office Action, the Examiner required restriction of one of the following 14 groups:

- Group I, consisting of claims 1-10, 24-25, 48-49, 54, and 57-78 drawn to a method to sterilize adventitious agents in a biological material.
- Group II, consisting of claims 1, 11-12, and 44, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging treatment with antioxidants.
- Group III, consisting of claims 1, 11, 13, and 45, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging treatment to remove lipids.
- Group IV, consisting of claims 1, 11, 14-15, and 46, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging treatment to withdraw metal ions with chelation.
- Group V, consisting of claims 1, 11, and 16, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging treatment to remove water.

- Group VI, consisting of claims 1, 11, 17-23, 47, and 55-56, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging treatment with radiations.

- Group VII, consisting of claims 1, 26-29, and 50-51, drawn to a method to sterilize adventitious materials in a biological product, wherein the product is packaged in two packages.

- Group VIII, consisting of claims 1, 30, 32-35, 53, and 64-65, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert gas.

- Group IX, consisting of claims 1, 30, and 61-63, drawn to a method to sterilize adventitious materials in a biological product, wherein the step of creating protective atmosphere for the package comprises exchanging the existing atmosphere with an inert gas and the adventitious agents are among: bacteria, fungus, mold, prions, virus, or yeast.

- Group X, consisting of claims 1, 30, and 66-69, drawn to method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert gas, wherein the packaged biological material is a donor none.

- Group XI, consisting of claims 1, 30, and 70-75, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert gas and subsequently subjecting said package to any one of the steps to remove one among: lipid, metal ions, water, reducing bio-burden, applying antioxidant or lowering the temperature of the biological material below ambient temperature.

- Group XII, consisting of claims 1, 30, and 76-88, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to treat the

product with an inert gas and subsequently with an ionizing radiation to reduce the bio-burden of said package.

- Group XIII, consisting of claims 1, 31, 36-39, 53, and 59-60, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to heat and cool said package and to sterilize said package in said heated or cooled state.

- Group XIV, consisting of claims 1 and 40-43, drawn to a method to sterilize adventitious materials in a biological product with irradiation.

In order to make a complete reply, the Applicant provisionally elects Group VIII, consisting of claims 1, 30, 32-35, 53, and 64-65, with traverse. The Applicant submits, as explained below, that the restriction requirement is improper and the Examiner has not met his burden for establishing the need for restriction.

The Examiner asserts that the various groups are independent and distinct. Specifically, the Examiner states:

> Inventions in Groups I-XIV are unrelated to each other because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP §806.04, §MPEP 808.01).

Office Action, p. 4, pp. 8. As noted, the Examiner refers to MPEP 806.04, which provides:

> Where an application includes claims directed to different embodiments or species that could fall within the scope of a generic claim, restriction between the species may be proper if the species are independent or distinct.

MPEP 806.04. MPEP 806.04(b) continues:

> Where species under a claimed genus are not connected in any of design, operation, or effect under the disclosure, the species are independent inventions.

MPEP 806.04(b). MPEP 806.04(b) then refers the reader to MPEP 802.01 and 806.06. MPEP 806.06 discusses independent inventions and provides:

> Inventions as claimed are independent if there is no disclosed relationship between the inventions, that is, they are unconnected in design, operation, and effect. If it can be shown that two or more inventions are independent, and if there would be a serious burden on the examiner if restriction is not required, applicant should be required to restrict the claims presented to one of such independent inventions. For example:
>
> (A) Two different combinations, not disclosed as capable of use together, having different modes of operation, different functions and different effects are independent. An article of apparel and a locomotive bearing would be an example. A process of painting a house and a process of boring a well would be a second example.
>
> (B) Where the two inventions are process and apparatus, and the apparatus cannot be used to practice the process or any part thereof, they are independent. A specific process of molding is independent from a molding apparatus that cannot be used to practice the specific process.

MPEP 806.06. Thus, the Examiner appears to be asserting that Groups I-XIV are unrelated in the same manner as, for example, an article of apparel and a locomotive bearing. Claim 1 is the only pending independent claim and is common to all the groups. Thus, at the very least, each group is directed to a method effective to protect a desired property of biological material during the process of sterilization. Accordingly, it is respectfully submitted that, at the very least, Groups I-XIV are not independent inventions as provided by MPEP 806.06.

Thus, the Groups set forth by the Examiner are related. In the Office Action, the Examiner further refers to MPEP 808.01, which provides:

> The particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should

> be concisely stated. A mere statement of conclusion is inadequate.
>
> For example, relative to a combination and a subcombination thereof, the examiner should point out the reasons why he or she considers the subcombination to have utility by itself or in other combinations, and why he or she considers that the combination as claimed does not require the particulars of the subcombination as claimed.
>
> Each relationship of claimed inventions should be similarly treated and the reasons for the conclusions of distinctness or independence set forth.

MPEP 808.01. MPEP 808.01(a) continues:

> Where there is no disclosure of a relationship between species (see MPEP 806.04(b)), they are independent inventions. A requirement for restriction is permissible if there is a patentable difference between the species claimed and there would be a serious burden on the examiner if restriction is not required. See MPEP 803 and 808.02.
>
> Where there is a relationship disclosed between species, such disclosed relation must be discussed and reasons advanced leading to the conclusion that the disclosed relation does not prevent restriction, in order to establish the propriety of restriction.

MPEP 808.01(a).

As discussed above, Groups I-XIV are necessarily related: Claim 1 is the only pending independent claim and is common to all the groups. Each group is directed to a method effective to protect a desired property of biological material during the process of sterilization. The Examiner provides no discussion of the relationship of the claimed inventions nor any reasoning following from the discussion of the relationship for why the relation does not prevent restriction. Indeed, the only explanation given by the Examiner is a mere statement of conclusion, which the MPEP itself declares is inadequate.

Accordingly, the Applicant respectfully submits that the restriction requirement is improper. The Applicant requests a restriction requirement fulfilling the Examiner's burden

establishing why the relation between the claims does not prevent restriction. Further, while the Applicant provisionally elects Group VIII, the Applicant respectfully submit that, at least, Groups IX, X, XI, and XII pose no additional burden to the Examiner for searching. Specifically, each of the claims included in Groups IX, X, XI, XII (claims 1, 30-39, 53, and 59-75) are identified by the Examiner as relating to treatment with inert gas:

- Group VIII, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert gas.

- Group IX, drawn to a method to sterilize adventitious materials in a biological product, wherein the step of creating protective atmosphere for the package comprises exchanging the existing atmosphere with an inert gas and the adventitious agents are among: bacteria, fungus, mold, prions, virus, or yeast.

- Group X, drawn to method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert gas, wherein the packaged biological material is a donor none.

- Group XI, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert gas and subsequently subjecting said package to any one of the steps to remove one among: lipid, metal ions, water, reducing bio-burden, applying antioxidant or lowering the temperature of the biological material below ambient temperature.

- Group XII, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert gas and subsequently with an ionizing radiation to reduce the bio-burden of said package.

Accordingly, the Applicant requests withdrawal of the restriction requirement at least between Groups VIII, IX, X, XI, and XII.

It is believed that no additional fees are due in connection with this communication. However, the Office is hereby authorized to charge any deficiency, or credit any overpayment to Deposit Account 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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